UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

February 20, 2008

DP BARCODE:		D348873
MRID:		47320201, 47320202, 47320203
SUBJECT:		Detox
REG. NO. OR FILE SYMBOL:		84368-R
DOCUMENT TYPE:		Product Chemistry Review
Manufacturing-use [ ]	OR	End-use Product [X]
INGREDIENTS (PC Codes):		001501
CAS Number:		64-17-5
TEST LAB:		OMC Ag Consulting, Mandala Technologies LLC, Product Development Services, LLC
SUBMITTER:		Mandala Technologies
GUIDELINE:		830 Guidelines
COMMODITIES:		Formulation
REVIEWER:		Chris Jiang CJ
ORGANIZATION:		AD
APPROVER:		Karen P. Hicks
APPROVED DATE:		2/20/08
COMMENT:		

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MEMORANDUM

Subject: Review for 84368-R

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34\Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies

Formulation from Label

Active Ingredient(s)	% by wt.
Ethyl alcohol	29.4 %
Other Ingredients	70.6 %
Total	100.0 %

BACKGROUND:

The registrant has submitted a label, a Confidential Statement of Formula (CSF) for the basic formulation, and MRIDs 47320201, 47320202, and 47320203 to fulfill the product chemistry guidelines for this integrated end-use product.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 13/02/2008) is consistent with the label declaration.

2. All ingredients are cleared for use in pesticidal formulations.

3. The product identity and composition is **unacceptable** because this guideline was not addressed.

4. The description of the starting materials is **unacceptable** because the CSF states that supplier of the pH adjuster is one company; however, the MSDS states that the supplier is another company. In addition, The CSF states that the purity of the pH adjuster is 45%; but the MSDS states that the purity of the pH adjuster is 100%.

5. The description of the manufacturing\production\formulation process is **unacceptable** because this guideline was not addressed.

6. The discussion of the formation of impurities is **unacceptable** because this guideline was not addressed.

7. The preliminary analysis is **acceptable**.

8. All certified limits are **acceptable**.

9. The enforcement analytical method is **unacceptable** because this guideline was not addressed.

10. MRID 47320201 states that the study contains Part A of the product chemistry requirements; however, this study only contains MSDS's and the Confidential Statement of Formula for the test substance.

11. The color, physical state, and odor are **unacceptable** because the test was not conducted under GLP compliance. The product is a clear colorless liquid with a mildly alcoholic odor.

12. The density is **unacceptable** as the test was not conducted under GLP compliance. The density was found to be 7.93 lbs/gal (0.95 g/mL).

13. The pH is **unacceptable** as the CSF states that the pH is 10; however, the study

states that the pH is 8.0. The study for pH was also not conducted under GLP compliance.

14. The oxidation/reduction potential is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

15. The flammability is **unacceptable** as this study was not conducted under GLP compliance. The flash point of the test substance was determined to be 84 °F.

16. The explodability is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

17. The storage stability is **unacceptable** because this guideline was not addressed. This study must be submitted under GLP compliance as confirmatory efficacy data was submitted with the application. The storage stability study is often conducted in conjunction with the study for corrosion charactereristics.

18. The viscosity is **unacceptable** as the study was not done under GLP compliance. The viscosity was determined to be 6.0 cps.

19. The miscibility is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

20. The corrosion characteristics are **unacceptable**. This guideline was not addressed. This study must be submitted under GLP compliance. The study for corrosion characteristics is often conducted in conjunction with the study for storage stability.

21. The dielectric breakdown voltage is **unacceptable** as this guideline was not addressed. This study must be conducted under GLP compliance.

22. The stability (guideline 830.6313), melting point (guideline 830.7200), and boiling point (guideline 830.7220) are not required for this product.

23. The label must read, "*Combustible.* Do not use or store near heat or open flame" if the flash point of the test substance was determined to be 84 °F.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the submission for 84368-R to be unacceptable for the reasons indicated in the findings. The registrant must remedy the issues discussed in the findings for registration to proceed.